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December 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket #97N-484S
Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To Whom It May Concern:

This letter is in regards to a recent proposal that donated human embryos be quarantined prior to use for reproduction. I strongly object to this proposal in that there is no evidence that donation of single cells, in particular oocytes, single sperm cells, or embryos as used with in vitro fertilization techniques have ever transmitted any type of infectious disease. The proposal is in error to assume that isolated, washed cells such as oocytes, sperm cells, or embryos have the same risk that donation of a vastly larger number of cells or body fluids such as semen, blood, or blood products. The fact that there has never been any report of transmission of disease with the technique of in vitro fertilization in over twenty years speaks to the low risk nature of the treatment. Quarantining embryos will significantly increase the costs of the treatment, which is already a great burden for the many unfortunate couples who rely on it as a treatment without any assistance from the health insurance industry or government. The success rate with in vitro fertilization would decrease by 50% and increase the costs by at least that much. By requiring cryopreservation of oocytes or embryos there will also be significant loss of genetic material and death of embryos.

Lastly, by mandating quarantining of oocytes, embryos, or isolated sperm cells, the government is interfering with the patient's right to choose their best treatment for their infertility. Infertile couples already have great obstacles to overcome and to present this proposal as a protection to them when there has been no demonstrable risk is not only unnecessary but also harmful to their goal.

Yours truly,

Susan P. Willman, M.D.

97N-4845

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SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY
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December 16, 1999

To: Practice, Medical, Laboratory and Individual members of SART

From: Philip I. McNamee, M.D., President

ALERT LETTER
ACTION NEEDED-LETTER TO FDA

The Food and Drug Administration has published in the Federal Register on September 30, 1999 proposed rules regarding donor egg IVF. Officially the proposed rules are titled "Suitability Determination for Donors of Human Cellular and Tissue-Based Products."

The entire proposed rules can be downloaded from www.fda.gov/cber/tissue/tissue.htm. While many of the proposed rules are acceptable, the most objectionable and totally unacceptable rule is the requirement to test an egg donor before the donor egg IVF cycle, freeze the resultant embryos and quarantine them until 6 months later when the egg donor is retested for infectious diseases. Only then are the embryos "suitable for embryo transfer."

We have until December 29, 1999 to respond to these proposed rules. SART AND ASRM have convened a task force to compose a reply. The reply strongly objects to these rules from scientific, legal, infectious disease, practical, monetary and medical practice aspects. The document is well researched and well referenced.

I am asking all Practice Directors and individual members of SART to also reply and object to this unnecessary intrusion into our medical practice. We would like to see a broad based (many practices) outcry. The responses do not have to be long and referenced. I am enclosing a fact sheet to assist you in your letter.

Please send your letters to: Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852
RE: Docket # 97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Thank you for your help. If you need further assistance call Joyce Zeitz, Executive Administrator of SART at 205-978-5000 ext. 109.

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Fact Sheet Re: Quarantining of Donor Embryos

1. There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal: HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.

2. Quarantining embryos will significantly increase costs and will increase the numbers of cycles needed to obtain the same pregnancy rate. (If you can estimate what that increased cost would be at your institute, please do so.)

3. Quarantining embryos will decrease the success rate for donor IVF. (If you can estimate the approximate decrease at your institute, please do so. The national average is about half).

4. There will be unnecessary deaths of embryos from the proposed rules to mandate freezing. (We estimate that possibly 9,000 embryos will be lost per year, representing a terrible loss of biological material and potential human lives.)

5. Increased delay causes anxiety and possible increased health risk in the woman delaying childbirth.

Summary: The FDA is interfering with the practice of medicine by attempting to require the quarantining of embryos resulting from donor egg IVF. There is no scientific justification (any transmission of HIV or other infectious disease) from IVF. Quarantining would increase costs, decrease success rate (pregnancy rate), and cause the unnecessary death of embryos and a delay in childbirth in an already older patient.

Finally, in the proposed rules, there seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk (so far no risk) associated with the use of isolated and washed sperm cells, oocytes and embryos.